PODS

Pulse Oximetery Data Analysis Software

CE 0473

User Manual

V 17.2 - October 2010

© 2005. Royal Liverpool University Hospital NHS Trust. All rights reserved. Not to be reproduced in whole, or in part, without the permission of the copyright holder.

Disclaimer:
This software is intended for use by qualified clinical professionals only in accordance with the guidelines set out in this manual and according to the user's own clinical judgment. Accordingly, save for liability for personal injury or death caused by negligence which is not excluded, all other liability of the Royal Liverpool University Hospitals NHS Trust is excluded.

1. Introduction

PODS (Pulse Oximetery Data Analysis Software) is a tool for downloading data from various pulse oximeters, store them on a computer and provide detailed analysis on the data. The method of analysis used in this software is based on clinically validated models which is widely accepted in medical practice [1,2]. The software enables the user to define groups and sub-groups of patients and plots the normative ranges for age and pathology-matched patients. The software also allows the user to update the database dynamically as new data is acquired. It provides detailed summary of the analysis results for each patient and visual representation of the comparison with the rest of the population.

The PODS software downloads and analyses oxygen saturation (SaO2) and heart rate (HR) data from the following pulse oximeters:

- NPB-595 pulse oximeter with software versions 2.4.6.0 and 3.0.0.0.
- Ohmeda Biox 3700/3700e.

☝ The software version in the NPB oximeter is displayed during power up

Throughout this manual, words highlighted in grey correspond to menu items in the software. Boxes with a ☝ symbol are notes to draw attention while boxes with **!** and bold text are warning notes.

2. Installation

Before you install this software, remove all old version by clicking on Add/Remove Software from the Control Panel. To install the software insert the PODS Setup CD in your PC, open the CD folder with Windows Explorer, double click on the setup

program and follow the instructions. Choose the default directory (C:\Program Files\PODS\) as a destination for the program.

! If you change the destination directory during setup, the program will not work properly

When you run the program for the first time on any PC, you will be prompted to enter a key. After entering the correct key, you will be offered the option to store the key in your computer so you do not have to enter it for subsequent use.

☞ The key is supplied separately

☞ During installation, you may get a version conflict message as some versions of the installed dll's may be older than existing ones. Answer 'Yes' to these messages to keep the newer version

3. Starting-up

During start-up, the program checks for the integrity of some system files which contain configuration and other vital data. If these files are tampered with, The program alerts the user that a security breach might have occurred. You might get this warning message if the program was not closed down properly e.g. as a result of a power cut, system crash or the user clicking the × button on the control box. A list of all files that might have been tampered with will be displayed and the user will be given a choice to continue. If the user chooses to continue, the attributes of these files will be restored to the correct settings.

4. File Menu

From the file menu, you can open files containing downloaded data, close files that are already opened, print graphs and reports and exit from the program.

4.1. Opening Files

You can view downloaded data by selecting 'Open' from the 'File' menu. Patient information will be displayed at the top and SaO2 and HR data will be plotted as trend graphs. Sections containing no data e.g. due to a disconnected probe are automatically filtered out and excluded from the analysis (see section 8).

4.2. Closing Files

Selecting the 'Close' menu item allows the user to close a file that has already been opened.

4.3. Printing

There are two menu options related to printing; 'Print' and 'Print Report'. The 'Print' option prints the active analysis mode (see section 5.1) with the patient data as a header. The 'Print Report' option on the other hand prints a customised-style report containing the cumulative analysis plot and a section for adding comments by handwriting which can go with the patient's notes.

4.4. Importing CSV Files

The user can import data from a CSV file (such as those downloaded from the Philips RDE software). From the file menu, choose the "Import" option. A window will open up which lists all the spreadsheets in the file. After selecting the appropriate spreadsheet, PODS will detect the number of samples in the sheet automatically. The user can change the number if they wish and click OK to proceed. The user then fills patient details and saves the file as before.

> ✍ There might be a slight delay after clicking save depending on the n umber of samples in which the computer might seem idle. A message will appear telling you to wait for the import procedure to complete.

5. Analysis Menu

The 'Analysis' menu item provides graphical and descriptive analysis of the data.

5.1. Graphical Analysis

There are 3 types of graphical analysis that can be chosen: 'Trends', 'Histograms' and 'Cumulative'. The 'Trends' and 'Histograms' modes display both SaO2 and HR data whereas the 'Cumulative' option displays SaO2 only. SaO2 data are plotted in blue and HR in red. In the 'Trends' mode, the mean value for SaO2 and HR can be displayed by selecting the 'Show Mean' menu item. The mean value will be displayed as a dotted line, superimposed on the raw data for the SaO2 and HR.

> ✍ In the Histograms mode, HR values are rounded up to the nearest decade before being assigned to a bin. For example, bin 70 contains all HR values from 65-74 bpm

5.2. Descriptive Analysis

A statistical summary of the data can be obtained by selecting the 'Statistics' option. This option will display a window containing the Total length of the study, the length included in the analysis, the length with no data and total length excluded from the analysis in hours. The total length excluded is the sum of length with no data plus any sections of the record that have been excluded from the analysis by the user due to motion artefact for example (see section 8). The 'Statistics' window also displays the Mean, Median Standard Deviation (SD) and Coefficient of Variation (CoV) parameters of SaO2 and HR. The total length of the download is provided and is broken down into (1) length included in the analysis, (2) length with no data and (3) length excluded by the user (see section 8). In this window, the user is offered the option to save the data as an MS Excel spreadsheet and print a summary.

6. Patient Details Menu

After opening a data file, patient details can be displayed by clicking the 'Patient Details' option from the main menu. At this point you may change the free notes section and save. You must however save the amended notes (with the data) into a different file.

✍ The maximum number of characters in the free notes section is 450. Double quotes (") and carriage returns are not allowed and will be replaced by an underscore (_) and a double space respectively

7. Chart Settings Menu

The 'Chart Settings' menu option is only available in the Trends mode. This option allows the user to alter some of x and y-axes properties.

7.1. Setting the X-Axis Scale

The 'Time Base' option allows the user to set the x-axis scale and plot the data in 4-hour, 8-hour sections or the full duration of the study

7.2. Annotating the X-Axis

Whilst data from the NPB 595 oximeter have their own time stamp, date and time information are not available with data downloaded from the Ohmeda Biox oximeter. The user can insert their own time annotation by clicking the 'Annotate Time Axis' option from the 'Chart Settings' menu. This option will provide text boxes at the bottom of each chart at equally distant intervals. The boxes will be marked as (12:00) initially. The user can change the text by double clicking on those boxes.

✍ The position of these text boxes is fixed and does not change when the time base is changed or when sections of the recording have been filtered out (Section 8). It is recommended that this option is only used as a rough indicator.

7.3. Setting the Y-Axis Scale

The default scale for the SaO2 chart is 0-100%. The default for the HR chart scale is 0 to maximum HR in the record rounded up to the nearest decade. The user can alter these scale limits by clicking the 'Y axis' option.

8. Artefact Menu

As mentioned earlier in section 4.1, any section of the study that contains no data (e.g. if the probe was disconnected) is automatically removed from analysis. The 'Artefact' menu item allows the user to exclude these sections and any other sections that contain unreliable information (e.g. motion artefact). This menu item is only available in the Trends display mode.

8.1. Manual Marking

Sections of the study that the user thinks may contain bad data can be manually marked by selecting the 'Mark' option. When this option is ticked, the user can click at the beginning and at the end of the section they wish to exclude on the trend line of the SaO2 chart. This will produce a grey section from the first to the second click. The user can generate an unlimited number of these blocks which can later be filtered out and excluded from the analysis. For example, suppose you wanted to exclude two sections of the recording in fig. (1) where excessive motion artefact is suspected. These sections are represented as sections A-B and C-D in fig. 1.

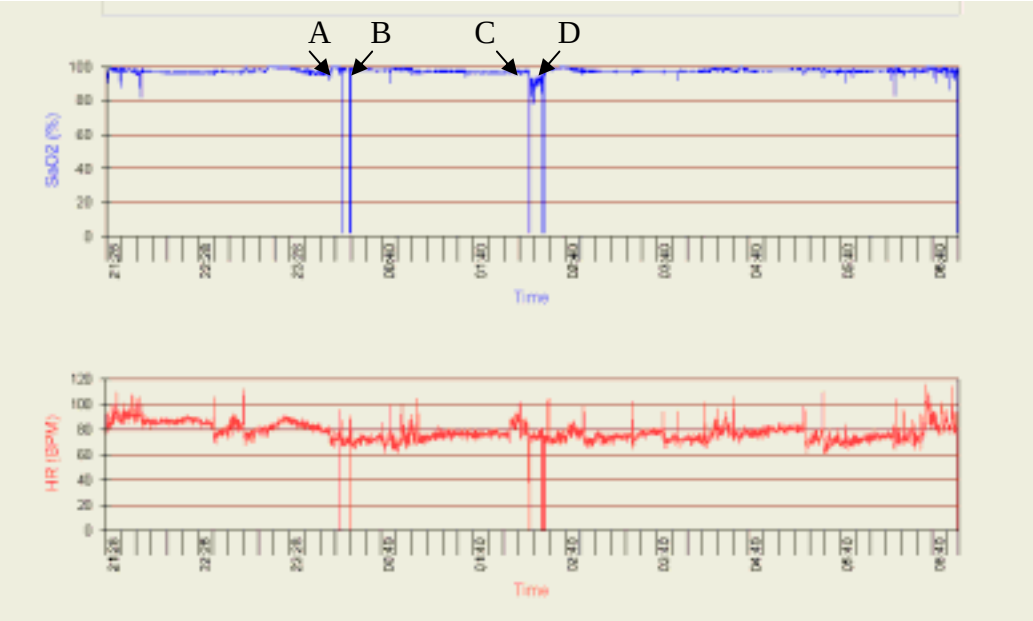


Fig. 1. A trend chart containing sections of bad data

First, click on the SaO2 trace near point A. A square-shaped marker appears on the trace where you clicked as shown in fig. 2.

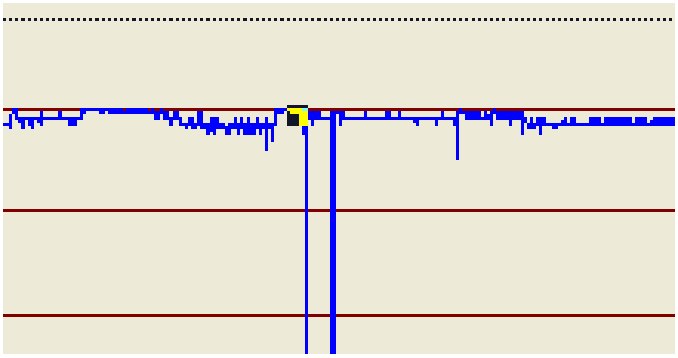


Fig. 2. Marking the beginning of the section to be filtered out

Next, click the SaO2 trace near point B. Another marker appears at this point and a grey block covers section A – B to show that it has been marked as shown in fig. 3.

Fig. 3. Marking the end of the section to be filtered out

☝ Point B must be after point A in time, i.e. the second click must be to the right of the first

Repeat these steps to produce as many grey blocks as required

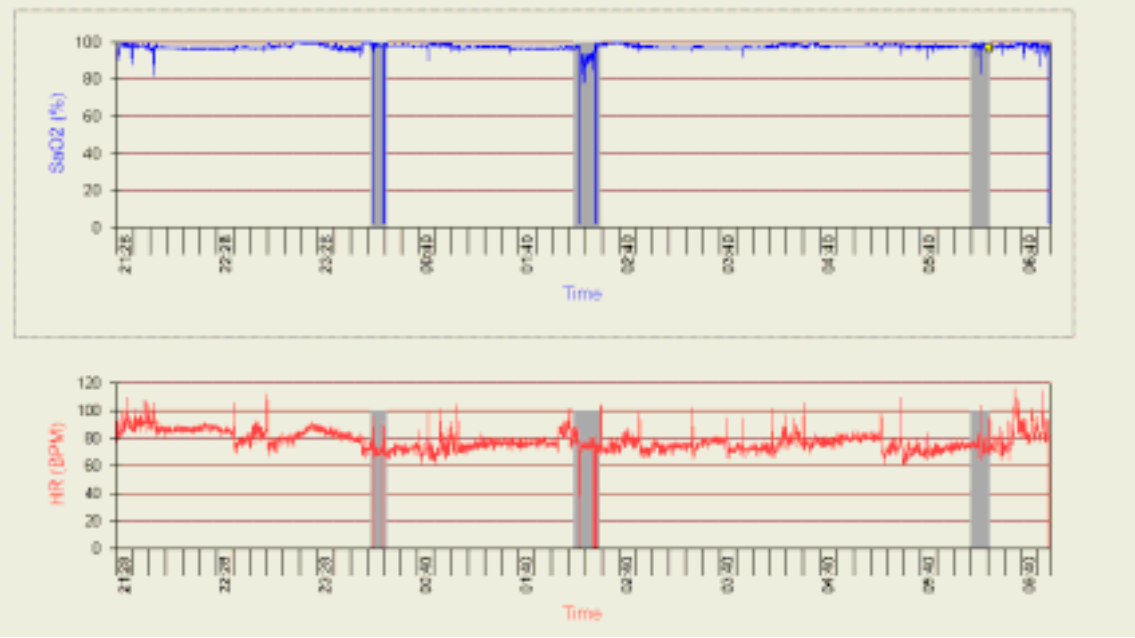
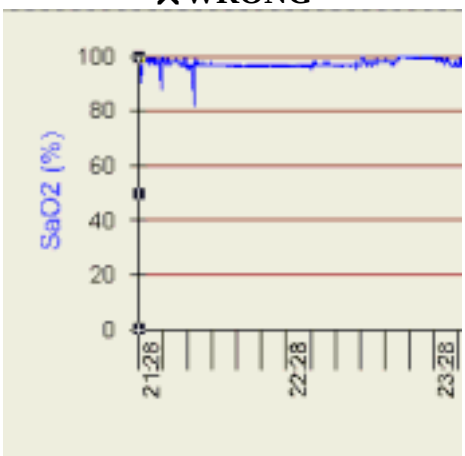


Fig. 4. Marking a number of sections to be filtered out

Sometimes, if you want to click on a point that is too close to the right or left y-axis, you might accidentally click on the axis itself rather than the trace. If this happens, 3 marker points will appear on the axis rather than a single one on the trace. You should therefore try clicking again until you see a single marker on the trace itself as illustrated in fig. (5).

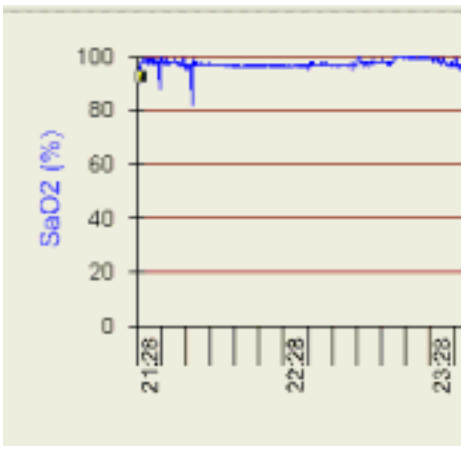
☝ Marker points and marked regions are not stored permanently. This information is lost when the file is closed. Software marked regions on the other hand where there are no data are permanently stored and they re-appear every time the file is opened.

✕WRONG



Three marker points on the y-axis

✓ CORRECT



A single marker on the trace

Fig 5. Marking a point close to the y-axis

8.2. Filtering

Grey blocks identified by the user can be excluded from further analysis by clicking the 'Filter' option. Filtered section are not deleted permanently from the disc and can be restored by closing and re-opening the data file.

8.3. Clearing Markers and Marked Regions

Marker points and marked regions can be cleared by clicking the 'Clear' button. This action will clear all points and regions including those with no data identified by the software.

9. Interface

The 'Interface' menu option allows the user to determine the communication settings, initialize a study and download data from memory

9.1. Coms Port and Device Setup

The 'Setup' option allows the user to choose the device, com port and baud rate to be used

9.2. Initializing a Study

The 'Initialize' option allows the user to initialize a study by entering patient details and setting the time and date of initialization. Before an oximeter is issued to a patient, the following checks need to be made:

- The oximeter's time and date are correct

  For the NPB 595, start with the monitor in the normal monitoring mode:

  1. Press the SETUP softkey.
  2. Press the NEXT softkey.
  3 Press the CLOCK softkey.
  4. Press the SET softkey.
  5. Press the SELECT softkey to select:
     TIME HOURS : MINUTES : SECONDS (16:46:05)
     DATE DAY - MONTH - YEAR (30-AUG-99)
  6. Use the ADJUST UP or ADJUST DOWN buttons to change the selected value.
  7. Press the EXIT softkey.

- The trend memory is cleared:

  For the NPB 595 with the monitor in the normal monitoring mode:

  1. Press the TREND softkey.
  2. Press the MONITR softkey.
  3. Press the NEXT softkey.
  4. Press the DELETE softkey.

  Note: Press the NO softkey and then the EXIT softkey to leave this function without deleting trend data.

  5. Press the YES softkey.

  All the trend data is cleared and the monitor sounds three beeps.

- Now return to the POBAB software. From the main menu:
  - Select Interface
  - Select Initialize

- Enter details and press confirm

! Make sure that the Equipment ID of the oximeter issued to the patient and the one entered in the PODS software match. It is recommended that a label is attached to the oximeter once it has been initialized stating the patient's name and date of the study.

9.3. Downloading Data From the NPB 595

Make sure that the oximeter's COMM protocol is ASCII. With the monitor in the normal monitoring mode:

1. Press the SETUP softkey.
2. Press the NEXT softkey.
3. Press the NEXT softkey.
4. Press the COMM softkey.
5. Press the ADJUST UP or ADJUST DOWN buttons to select the desired baud rate.
6. Press the SELECT softkey to select protocol.
7. Press the ADJUST UP or ADJUST DOWN buttons to select the desired protocol.
8. Press the EXIT softkey.

Now return to the POBAB software. From the main menu:

1. Select Interface and Setup
2. Select the desired Comms port and Baud Rate and Press OK to return to the main menu
3. Select Download
4. Select a patient from the list of outstanding studies
5. Enter the Equip ID number of the oximeter used
6. If this is correct the download button is enabled
7. Press Download and enter a filename to save the data into
8. You should be able to see a flashing disk picture and a counter
9. If no activity is detected after 10 seconds, the download process times out
10. The numbers in the counter should increment quickly. If the number stays on "0" or increments slowly (about once every 4 seconds) the download is not successful. Refer to Troubleshooting.
11. When the download is complete, a "Download Complete" label appears. Press the Exit button to return to the main menu.

10. Cumulative SaO2 Analysis

Cumulative analysis of SaO2 data can be carried out by clicking the 'Cumulative' option from the 'Analysis' menu. Cumulative data can be displayed and compared with normative data and with age and/or pathology matched cohorts.

10.1. Defining Groups According to Age and Pathology

The user can define up to 3 age groups and 3 pathology groups to suit their own clinical needs. For example, the following age groups can be defined:

- Group 1: < 1 year
- Group 2: 1-18 years
- Group 3: > 18 years

and the following pathology groups might be defined:

- Group 1: Normal
- Group 2: Asthma
- Group 3: Bronchitis

10.2. Building a Cumulative Database

Suppose a clinical trial gathered data from 10 normal adult volunteers and 10 adults with asthma. After filtering out any bad data and clicking the 'Cumulative' option, the user can then press the 'ADD' button on the bottom left hand corner of the screen. After entering the correct password, the user will then be prompted to enter the age and pathology group that the record belongs to. The user selects >18 and Normal for each record in the first group and > 18 and Asthma for the second group. The user will be asked to confirm before a record is added to the database. In order to avoid bias, each record cannot be entered into the database more than once. If the user clicks on the 'ADD' button on a record that has been previously added to the database, an error message is displayed.

10.3. Comparing Cumulative Curves

Supposing a cumulative curve of a 15 year old asthmatic is displayed. We can make the following comparisons by clicking the 'Choose Cumulative Curves' button:

1) Age-matched group by selecting 1-18 on the age group and All on the pathology group
2) Pathology-matched group by selecting All on the age group and Asthma on the pathology group
3) Age and pathology-matched group by selecting 1-18 on the age group and Asthma on the pathology group
4) The whole database by selecting All on both groups

When a group is selected, two curves are plotted superimposed on the record under analysis. These curves represent the 50^{th} and 5^{th} centile of the group. In addition, the number of record in the selected group and the last time it was updated are displayed.

> ✍ The software creates a temporary Excel spreadsheet called TempCum.xls in the (C:\Program Files\POBAB\) directory containing data from the last group selected for cumulative analysis. The spreadsheet puts cumulative data from each record in that group in a single row with 16 columns representing the frequency in bins 85-100% inclusive. At the bottom, there is a gap of 4 rows followed by two rows representing the 50^{th} and 5^{th} centile data respectively for each bin. This file might be useful for off-line analysis and for generating group summary graphics. The file is overwritten every time a group is selected.

10.4. Backing Up the Database

The cumulative database can be backed up by selecting the 'Backup' option. In addition to the cumulative data, you can also backup the group definitions and patient lists. If you backup to a destination that already contains these files, a warning message will be displayed that old files will be overwritten.

! The software does not offer an option to backup individual data records. These files should be regularly backed up and protected from corruption by the user.

10.5. Restoring the Database

The cumulative database can be restored up by selecting the 'Restore' option. In addition to the cumulative data, you can also restore the group definitions and patient lists. A warning message will be displayed that old files will be overwritten.

11. Software Version

The software version in use can be determined by clicking the 'About' item from the main menu.

12. Troubleshooting

If you experience difficulties when downloading try the following:

1. Make sure that the oximeter is plugged to the mains and switched on
2. Make sure the serial link cable between the oximeter and the PC is firmly in place
3. Make sure that the data are still in the memory and have not accidentally been erased. **Note**: Erasing the memory can only be done with the oximeter as described above and can not be done by the PODS software
4. Make sure that the oximeter's COMMS protocol is on ASCII as described above
5. Make sure that the PODS COMMS setup (port number and baud rate) are correct as described above
6. Make sure that the date and time on the oximeter are correct
7. Make sure that the date and time entered at the initialisation stage are correct
8. If you still can not download, please contact the software developers:

Department of Clinical Engineering
Royal Liverpool University Hospital NHS Trust
1st Floor, Duncan Building
Daulby Street
Liverpool L7 8XP
Tel: 0151 706 4202
Fax: 0151 706 5803
website: www.clineng-liverpool-nhs.com

References:

1) Ng A, Subhedar N, Primhak RA, Shaw NJ. 1998. "Arterial oxygen saturation profiles in healthy preterm infants". Arch Dis Cild fetal neonatal ED; 79:F64-F66
2) Michael S. Urschitz, Judith Wolff, Volker von Einem, Pilar M. Urschitz-Duprat, Martin Schlaud, Christian F. Poets. 2003 "Reference Values for Nocturnal Home Pulse Oximetry During Sleep in Primary School Children". Chest; 123-1: 96-101.